

**REMARKS**

The Office Action mailed August 11, 2004, set a three-month statutory period for response expiring November 11, 2004. This response is therefore timely filed.

Claims 1, 3, 4, 6-9, and 11-34 are in the application.

Claims 24 and 34 are withdrawn from consideration as being drawn to non-elected subject matter.

Claim 17 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite on the grounds that the term "other" renders the claim indefinite because it is not clear what "other galenic entity" contains the active substance. The Examiner suggests that the term "other galenic entity" be replaced with sustained or immediate release entity.

This rejection is believed overcome by the foregoing amendments to claims 16 and 17 whereby the phrases "another galenic entity" and "other galenic entity" have been replaced with the phrase "sustained release entity or immediate release entity," as suggested by the Examiner.

Claims 1, 3, 4, 6-9, 11-23, and 25-33 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Chen et al. (U.S. Publication No. 2003/0077297) in view of Lerner et al. (U.S. Patent No. 5,840,332) on the basis that Chen discloses tablets, pellets or beads of active agents, and the active particles may be contained within a capsule, and that diclofenac, indomethacin, and an extended list of drugs can be formulated according to the disclosure of Chen. The Examiner also states that the pharmaceutical compositions of Chen contain ammonio methacrylate copolymers and zwitterionic surfactants. While acknowledging that Chen fails to teach a coating with the A or B type EUDRAGIT, the Examiner maintains that Lerner discloses

that similar drugs such as diclofenac and indomethacin particles can be coated with the A or B type EUDRAGIT. The Examiner concludes that one of ordinary skill in the art would have been motivated to coat particles of diclofenac with A or B type ammonio methacrylate copolymers with the expectation of producing a dosage form with the desired delayed/sustained release of the drugs. The rejection is respectfully traversed and reconsideration thereof is requested.

Initially, it is noted that the Chen et al. reference (U.S. Patent Application Publication No. 2003/0077297) has a publication date of April 24, 2003, which date is after applicants' claimed foreign priority date of June 28, 1999, and international filing date of June 27, 2000. Therefore, the Chen reference is not available as a reference under 35 U.S.C. § 102(a)/103 or 35 U.S.C. § 102(b)/103 against the instantly claimed invention. Moreover, Chen et al. has a filing date of February 11, 2002, and, thus, is unavailable as a prior art reference under 35 U.S.C. § 102(e)/103.

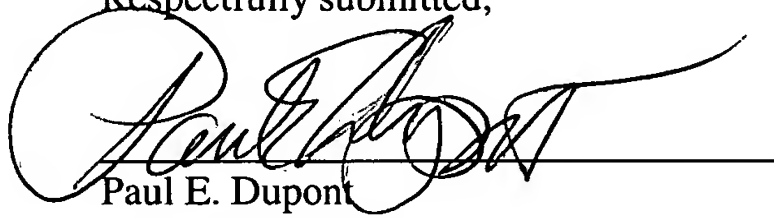
Inasmuch as the instant rejection is based on Chen's earliest effective filing date of February 26, 1999, the portions of Chen relied upon for this rejection must necessarily be found in the disclosure of Chen's grandparent application (U.S. Patent No. 6,294,192, issued to Patel et al., filed on February 26, 1999) for Chen to be available as prior art under 35 U.S.C. § 102(e)/103. Applicants respectfully submit that the portions of Chen et al. principally relied upon by the Examiner for the instant rejection are not disclosed in Patel et al, U.S. 6,294,192. Specifically, the Examiner primarily relies upon Chen for the alleged disclosure of core active drug particles coated with EUDRAGIT polymers. However, Patel fails to disclose EUDRAGIT polymers or any other ammonio methacrylate copolymers, and moreover fails to describe a core of active substance coated with a polymer comprising an ammonio methacrylate copolymer, as required by applicants' invention. Thus, as the Patel reference clearly fails to disclose the portions of Chen relied upon by the Examiner for the instant rejection, the filing date of February

26, 1999, for the Patel patent is irrelevant to the rejection at bar, and, therefore, the Chen reference is not available as prior art under 35 U.S.C. § 102(e)/103 against the instant invention.

Accordingly, the Chen reference is clearly not available as a reference under 35 U.S.C. § 102(a)/103, 35 U.S.C. § 102(b)/103, or 35 U.S.C. § 102(e)/103 against the instantly claimed invention and, hence, the rejection under 35 U.S.C. § 103(a) based on Chen et al. in view of Lerner et al. is unwarranted and should therefore be withdrawn.

There being no remaining issues, this application is believed in condition for favorable reconsideration and early allowance, and such actions are earnestly solicited.

Date: 11/2/04  
Address:  
Sanofi-Synthelabo Inc.  
9 Great Valley Parkway  
P.O. Box 3026  
Malvern, PA 19355  
Tele: (610) 889-6338  
Fax: (610) 889-8799

Respectfully submitted,  
  
Paul E. Dupont  
Reg. No. 27,438